Low Risk Participant Information Sheet and Consent Form Guideline

Overview

The purpose of the Participant Information Sheet and Consent Form (PICF) is to "provide information about research and its requirements so that the prospective participant can decide if they wish to take part in the research."

The PICF must be participant centred. It is therefore important that the PICF is written in language that is appropriate to the demographic of prospective participants. Researchers should consider factors such as age, language, literacy and level of education when writing PICFs.

The CALHN HREC encourages the use of the NHMRC endorsed Information Sheet Templates available here. However, for low risk studies, a simpler version may often be appropriate.

This document provides a guide only. It is not intended to be used as a template. Low risk health and medical research is a very broad area. Researchers may need to delete some sections and add others so the PICF suits their particular research project.

Sentences should be kept short and paragraphs should be kept concise. The PICF should be written using an active voice rather than passive, and should use personalised language ('we' and 'you'). Legal jargon and medical terminology should be avoided where possible.

Researchers should also consider the presentation of the PICF. Information should follow a logical structure. Paragraphs should be well spaced and kept short. Sections should be clearly marked with numbered headings. Lists should be numbered or bullet pointed. Key information should be highlighted via typeface or by being clearly separate from other information in the form.

PLEASE NOTE: All documents submitted for review must contain the document label, version number, date, page number, and total number of pages in the footer. The logo of the organisation that will own the study results is inserted in the header.

Document Formatting:

Logos:	The institution/organisation that will own the study results
Font:	Arial (default)
Alignment	Left align the text
Desirable footer format:	<Document type>, Version XX, Dated XX XXX XXXX Page X of X

Government of South Australia
Health
Central Adelaide Local Health Network

Participant Information Sheet

Project Title:

Short Title: *(If applicable)*

HREC Reference:

Project Sponsor: *(The institution responsible for the ownership of the protocol/results)*

Principal Investigator:

Location(s):

1. Introduction

The introductory paragraph should invite the reader to participate in the study, and explain why they have been recruited.

2. What is the purpose of this research?

Briefly state the purpose of the research and provide an overview of the study.

If the research is also for the purpose of obtaining an educational qualification for one more of the investigators, this must be specified.

3. Who is undertaking this research?

Identify the investigators and their employer/educational supervisory institutions.

If the research is part of a multi-institutional collaboration, or is funded by corporate sponsorship or a grant, this must also be specified in the PICF.

4. Do I have to take part in this research project?

The following statement must be included in all PICFs:

This is a research project and you do not have to be involved. If you do not wish to participate, your <select: [medical care]/[employment]> will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.

5. What does participation in this research involve?

This section should describe, in plain language, exactly what the participants will experience when participating in the study. Each aspect of participation should be explained separately.

If participants are required to attend a site as part of the study, the exact location must be provided in the PICF.

Where information from participants' medical (or other) records is required for the study, the following information must be provided in the PICF:

- The source of the records
- The type of information that will be extracted from the records

- Who will be accessing it
- How it will be accessed (eg. any transfer between institutions).

Any financial or other reimbursement for participants' time or costs incurred from participation in the study should be specified in this section.

6. What do I have to do?

Specify any additional activities or restrictions (eg. medication, diet, exercise) that the participants must undertake in order to successfully participate in the study.

Any pregnancy exclusions must be clearly highlighted.

If no additional action is required, this must also be made clear to participants.

7. What are the possible benefits of taking part?

Many studies do not have any direct benefit to participants. If this is the case it must be clearly stated.

Note: financial/other reimbursement for participation is not a benefit of the study.

8. What are the possible risks and disadvantages of taking part?

Explain the potential risks participants may face, and any disadvantages they may experience from participating in the study. Consider:

- Physical harm
- Psychological distress
- Financial harm
- Harm to reputation.

As research is never 100% risk free, the phrase 'no foreseeable risks' should be used rather than 'no risks'.

9. Can I have other treatments during this research project?

Provide details of any treatments that participants cannot undertake while participating in the study.

If participants can continue their usual treatment course, this must be clearly stated.

10. What will happen to the information about me?

State whether data collected will be de-identified, re-identifiable, identifiable but confidential or anonymous.

Explain the study's data confidentiality and security measures:

- Form of stored data
- Location of storage
- Who has access
- How it is secured
- Duration of storage
- Method of destruction.

Describe the method of dissemination of study results (for example academic journal publication, conference, internal institutional publication).

Clearly state whether participants will be identifiable in any publications.

The following statement must* be included:

'In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.'

*<*If re-identification of data will not be possible or if data will be anonymous then there is no need to include the above privacy/data access statement>*

11. What will happen to my test samples?

Provide details about the storage of any test samples collected in the study, including:

- Identifiability
- Location of storage. *This should be at the site that will own the study results.*
- Who has access?
- How it is secured?
- Duration of storage. *This should be a minimum of five years post study completion.*
- Method of destruction.
- Who will be responsible for ensuring data destruction?

12. What happens if I withdraw from the research?

Reiterate that participants are free to withdraw any time.

Explain what will happen to any information collected prior to a participant's withdrawal from the study.

If the research involves dependent or unequal relationships, include that non-participation or withdrawal will not affect ongoing treatment/medical care.

13. What happens if I am injured from taking part in the study?

Describe any compensation schemes particular to the study.

Include the following statement:

Your participation in this study shall not affect any other right to compensation you may have under common law.

14. Complaints and Contacts

The following statements must be included in this section:

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chairperson, on 7117 2229.

NOTE: For multi-site studies, an independent contact must be nominated for each site.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

For matters relating to research at the site at which the participant is participating, the details of the local site person:

Local Research Governance Office Contact *(if applicable)*

Name	
Position	
Phone	
Email	

Research Contact

Name	
Position	
Phone	
Email	

Note: *A study team member should be listed as a 'Questions and Information' Contact. Study team members must not be listed as a Complaints Contact as this must be the HREC Support Officer as outlined above.*

Participant Consent Form

Project Title:

Short Title: *(If applicable)*

HREC Reference:

Project Sponsor: *(The institution responsible for the ownership of the protocol/results)*

Principal Investigator:

Location(s):

The consent form should include the following statements:

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- The nature, purpose and risks of the research project have been explained to me. I understand them and agree to take part.*
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.

If participants are receiving reimbursement, include the statement:

- I understand the statement about reimbursement and costs contained in the Information Sheet.

If the study involves pregnancy exclusion, include the statement:

- I understand that I must not be pregnant or become pregnant during the course of the study.
- I understand that if I do become pregnant I must notify the researchers immediately.

* If there are particular/unusual risks involved in the study (even if they are low in likelihood or level of harm), they may need to be included as a specific item in the consent form.

Name of Participant (please _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness to informed consent is required*

Name of Witness* to Participant's Signature (please print) _____

Signature _____Date _____

** Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.* ***REMOVE IF NOT APPLICABLE***

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks, and the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature

For more information:

CALHN Research Services
T: (08) 7117 2224
E: Health.CALHNResearchLNR@sa.gov.au